

Remarks

Claims 1-64 were examined and acted upon in the aforesaid Office Action. No claims have been canceled and new claims 65-67 have been added, leaving claims 1-67 for further consideration.

Claims 13, 14 and 35-64 have been rejected under 35 U.S.C. 101 as drawn to parts of a human body.

Claims 13 and 14 have been amended to make clear that the adjacency of the first vertebra and the second vertebra is descriptive of the spinal area to which the prosthesis is applied. No vertebra is set forth as a claimed element of the kits defined by claims 13 and 14.

Reconsideration of the rejection of claims 35-64 under 35 U.S.C. 101 is respectfully requested. Referring to claim 35, the language in question recites "said prosthesis comprises a replacement for a posterior element of a structural vertebra, wherein the natural vertebra comprises a natural vertebra body,...natural pedicles...a natural lamina...natural superior facets...natural inferior facets...a natural spinous process...natural transverse processes..., said prosthesis comprising:" thereafter are recited elements positively claimed, i.e., prosthetic

mounts...prosthetic lamina...prosthetic superior facets...prosthetic inferior facets...prosthetic spinous process. The natural body parts are set forth by way of a preamble, setting the stage for the application of the various prosthetic parts. It is believed that the delineation between the invention and the body area of use of the invention is clear.

Claims 38, 41, 44, 46, 49, 52, 57 and 61 are drawn in much the same fashion.

It is believed that claims 35 and those recited immediately above are in correct form and that the 35 U.S.C. 101 rejection should be vacated.

Claim 11 stands rejected under 35 U.S.C. 112 as lacking an antecedent. Claim 11 has been amended to correct the antecedent problem.

Claims 1-64 stand rejected under 35 U.S.C. 103(a) as unpatentable over Reiley in view of Ray.

Riley provides a number of spinal joint replacement assemblies, particularly protheses for replacement of structural facet joints. Riley dismisses disc replacement as helping mainly those patients with injured or diseased discs. Riley notes that disc replacement does not address spine pathologies

such as spondylobisthesis and spinal stenosis (col. 3, lines 30-40). Riley believed that the need lay with prostheses for replacing injured and/or diseased facet joints.

Ray is concerned with displaced or diseased spinal discs, but does not propose to provide a replacement disc. Ray notes (col. 1, lines 36-42) that a disc is comprised of three components, (1) nucleus pulposis ("nucleus"), (2) annulus fibrosus ("annulus"), and (3) two opposing end plates. Ray provides trial implants of about the size of a disc nucleus to assist in inserting a replacement nucleus in a disc. Ray's invention is directed toward determining the volume of a disc nucleus so as to implant a replacement artificial nucleus of a correct size. Apparently, artificial nucleuses are expensive and once inserted, even if briefly and withdrawn, as from attempting to insert the wrong size, cannot be used again because of difficulty of sterilization.

New claim 65 sets forth a kit including an artificial disc and a prosthesis for a vertebra. It is believed that no one has heretofore combined these two elements in a single kit for complementary interoperation.

Riley is directed only to facet joints and teaches against the benefits of disc replacement.

Ray is directed to discs, but not to replacing discs, but rather to making easier the insertion of correctly sized nucleuses into the intradiscal space. Thus, Ray is not even directed to disc replacement, and certainly not disc and facet prostheses combinations.

Accordingly, it appears that the claimed combination is not taught or suggested by the Riley and Ray references and that claims 1-67, all of which are directed to just such a combination, should be deemed allowable thereover.

Allowance of claims 1-67 is therefore most respectfully requested.

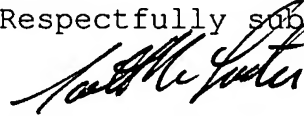
In reviewing the application, a number of minor errors were noted in the specification and have been corrected herein. Similarly, some errors and omissions were noted in the drawings. In FIG. 16, the lead line for reference character 26 has been extended. In FIG. 23, reference character 1095 has been inserted in place of an incorrect reference character. In FIG. 51, reference character 2730 has been added (two places). In FIG. 52, reference character 2830 has been added (two places).

- 45 -

In the event that any fees may be required in this matter,
please charge the same to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,



Scott R. Foster

Registration No. 20,570

Pandiscio & Pandiscio

470 Totten Pond Road

Waltham, MA 02451-1914

Tel. (781) 290-0060

KK/MED3.AMD

MED-3